

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS**

No. 08-0308V

Filed: August 26, 2013

Osob Hashi, by SAFIA WEGED and
HUSSEIN H. HASHI, her parents,

Petitioners,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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Autism; Statute of Limitations; First
Symptom or Manifestation of Onset;
Significant Aggravation

Elaine W. Sharp, Esq., Whitfield, Sharp & Sharp, Marblehead, MA, for petitioners.
Traci R. Patton, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

ORDER AND RULING DISMISSING CAUSATION IN FACT CLAIM¹

Vowell, Special Master:

On May 17, 2012, respondent filed a motion to dismiss this claim, asserting that the petition was untimely filed. Petitioners filed their response to respondent's motion on July 16, 2012. Although their amended petition, filed June 29, 2011, asserted only an actual causation claim, petitioners appear to rely on a significant aggravation claim in their response.

For the reasons set forth below, I dismiss petitioners' causation in fact claim. If petitioners intend to rely upon a significant aggravation claim, they shall file a second amended petition setting forth the facts upon which such claim is based by September 25, 2013. Petitioners are also hereby ordered to file an expert report to support their significant aggravation claim by November 25, 2013. Such a report must clearly indicate the expected progression of Osob's disorder and how that progression was altered by vaccines received less than 36 months from the date of filing of the original petition in this case. If the expert relies upon facts other than those set forth in Section

¹ Because this ruling and order contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

Below, the expert must identify the source of the information upon which he or she relies, and explain why he or she does so.

I. Procedural History.

On April 22, 2008, Safia Wedged and Hussein Hashi ["Ms. Wedged," "Mr. Hashi," or "petitioners"] filed the short-form petition authorized by Autism General Order #1² for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*³ [the "Vaccine Act" or "Program"], on behalf of their minor daughter, Osob Hashi ["Osob"]. By filing the short-form petition, petitioners joined the Omnibus Autism Program ["OAP"],⁴ thereby asserting that Osob has an autism spectrum disorder ["ASD"]⁵ and that one or more vaccines listed on the Vaccine Injury Table⁶ were causal of her condition. Petitioners did not file any medical records or details regarding Osob's injuries with the short-form petition.

On April 28, 2008, the presiding special master⁷ ordered petitioners to complete their petition by filing the statutorily required medical documentation⁸ and a "Statement Regarding Onset," clearly detailing Osob's first symptom or manifestation of onset or significant aggravation of her injury. Order, issued Apr. 28, 2008. Respondent filed her Rule 4(c) report on May 20, 2008, noting that petitioners had yet to file any evidence and thus, she could not assess the merits of the claim without the medical records. Respondent's Report ["Res. Rpt."] at 4. By October 23, 2008, petitioners filed 23 exhibits of medical records,⁹ but did not submit a "Statement Regarding Onset."

² The text of Autism General Order #1 can be found at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf>, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002).

³ National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

⁴ The OAP is discussed in detail in *Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

⁵ "Autism spectrum disorder" is an umbrella term encompassing several neurological disorders manifesting in early childhood with impairments in communication and social interaction, and the display of restricted, repetitive, or stereotypical patterns of behavior, interests, and activities. A more complete description of the disorder is contained in *White v. Sec'y, HHS*, No. 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011).

⁶ 42 C.F.R. § 100.3 (2011).

⁷ This case was reassigned to me on July 1, 2011.

⁸ Section 11(c)(2) of the Vaccine Act and Vaccine Rule 2 requires that the petition be accompanied by medical records and affidavits.

⁹ Petitioners initially labeled their 23 exhibits A-W. The National Vaccine Injury Compensation Program Guidelines for Practice indicates that petitioners' exhibits should be labeled using Arabic numbers. Accordingly, petitioners refilled most of these exhibits using numbers as Petitioners' Exhibits ["Pet. Exs."] 1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, and 3. However, I was unable to locate Petitioners' Exhibit S in the

No further activity occurred in this case until after the conclusion of the appeals in the OAP test cases. On January 25, 2011, in view of the test case findings of insufficient evidence linking vaccines and autism, petitioners were ordered to inform the court if they wished to proceed with their claim or if they wished to exit the Vaccine Program. If they wished to proceed, petitioners were ordered to file an amended petition. Order, issued Jan. 25, 2011. Petitioners filed their amended petition on June 29, 2011, alleging that the measles, mumps, and rubella ["MMR"] vaccine Osob received on July 1, 2002, caused an encephalopathy and sequelae. Amended Petition ["Am. Pet."] at ¶ 2-3. The amended petition also alleges that Osob was later diagnosed with a mitochondrial disorder, specifically a Complex I Electron Transport Chain ["ETC"] deficiency. *Id.* at ¶ 4.

This case was reassigned to me on July 1, 2011. During a status conference held on July 20, 2011, I advised petitioners' counsel that this claim appeared to have been filed outside the Vaccine Act's 36 month statute of limitations. I cautioned petitioners' counsel against obtaining an expert report at that time, in view of the unsettled state of the law regarding the Vaccine Act's statute of limitations and its effect on payment of fees and costs on unsuccessful cases.¹⁰ Order, issued July 20, 2011.

Between August 3, 2011, and October 18, 2011, petitioners filed a total of eight additional exhibits addressing Osob's more recent medical treatment. Shortly thereafter, petitioners' counsel reported that neuro-geneticist Katherine Sims had been retained as an expert to evaluate claims of vaccine causation and an expert report was forthcoming. Petitioners' Status Report, filed Oct. 19, 2011.

In response to petitioners' status report, I reiterated my caution about retaining an expert prior to a determination that this case was timely filed. I emphasized that, given Osob's age and ASD diagnosis at the time this petition was filed, a significant issue in this case was an absence of records of Osob's routine pediatric care from birth onward, and I ordered petitioners to refocus their efforts toward developing a complete medical record. Order, issued Nov. 1, 2011. Additionally, I ordered petitioners to provide medical records identifying the physician or other specialist who diagnosed Osob with ASD. Order, issued Dec. 2, 2011.

Between early December 2011 and April 2012, petitioners filed eight additional exhibits containing Osob's educational and medical records from birth to early childhood. During this time, petitioners submitted a status report indicating that Osob

subsequently filed documents, and it continues to be identified as Pet. Ex. S in his ruling.

¹⁰ At the time of this status conference, interpretation of the Vaccine Act's statute of limitations was under review by the U.S. Court of Appeals for the Federal Circuit. The Federal Circuit, sitting *en banc*, heard oral argument in *Cloer v. Sec'y, HHS*, on May 10, 2011. Because the outcome of that case could affect my determination of timeliness in this case, I opted to wait for the Federal Circuit's decision before ordering petitioners to obtain an expert report. On August 5, 2011, the Federal Circuit reiterated that the first symptom recognized by the medical community at large as a symptom of a disorder triggered the running of the statute of limitations in Vaccine Act cases. *Cloer v. Sec'y, HHS*, 654 F.3d 1322 (Fed. Cir. 2011), *cert. denied*, 132 S. Ct. 1908 (2012).

suffered a pre-existing injury, specifically a mitochondrial disorder, which was exacerbated by repeated vaccinations. Status Report, filed Dec. 16, 2011. However, the report did not identify which specific vaccines were believed to have aggravated Osob's disorder.

On May 17, 2012, respondent filed a motion to dismiss petitioners' claim, arguing that the petition was filed approximately two years and four months after the expiration of the statute of limitations.¹¹ Respondent's Motion to Dismiss ["Res. Mot."] filed May 17, 2012, at 5 (noting that the petition should have been filed by December 31, 2002). In response, petitioners filed a joint opposition to respondent's motions to dismiss in both of their children's cases.¹² In their opposition, petitioners assert that the diphtheria, tetanus, acellular, and pertussis ["DTaP"], MMR, and inactivated polio virus ["IPV"] vaccines administered on April 22, 2006,¹³ significantly aggravated Osob's pre-existing mitochondrial disorder and that the short-form petition was filed on April 22, 2008, within the statute of limitations period.¹⁴ Petitioners' Joint Opposition to Respondent's Motions To Dismiss ["Pet. Opp."] at 2, 5.

As I indicated in my September 6, 2012 order, the filed medical records showed that Osob received DTaP, MMR, and IPV vaccines on April 24, 2006, but did not include Dr. Peter Masucci's consultation notes from that date or any particulars about the vaccinations, such as the lot number or manufacturer. Order, issued Sept. 6, 2012. Petitioners then filed Dr. Masucci's complete consultation notes for Osob's visits occurring between March 2005 and August 2006 as Pet. Ex. 18.

II. Facts.

A. Osob's Early Health and Development.

Osob was born on June 30, 2001.¹⁵ *See generally*, Pet. Ex. 13. She received a hepatitis B vaccine prior to her discharge from the hospital and continued to receive routinely-administered childhood vaccinations in her first year of life, without apparent ill

¹¹ The Vaccine Act provides that "no petition may be filed . . . after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury." § 16(a)(2).

¹² In addition to this case, petitioners have filed a petition on behalf of their daughter Sahra. (No. 08-307V).

¹³ The record petitioners cited for this date, Pet. Ex. 7, pp. 2-3, is a visit from June 9, 2007. I note that the date of the DTaP, MMR, and IPV vaccines listed in Osob's consultation notes is April 24, 2006, and not, as petitioners allege, April 22, 2006.

¹⁴ This claim differs from petitioners' amended petition, which identified the July 2002 MMR vaccine as causing Osob's encephalopathy and sequelae. Am. Pet. at ¶ 3.

¹⁵ Records indicate that Ms. Wedged had gestational diabetes and that there was moderate meconium staining in the amniotic fluid, which may indicate a degree of fetal distress. However, Dr. Stratton noted that Osob was a well newborn. Pet. Ex. 13, pp. 141-42.

effects. *Id.* At six months of age, pediatrician Dr. Lawrence Stratton described her as having excellent growth. *Id.*, p. 128.

1. Onset of Developmental Delay.

Doctor Stratton first expressed concerns about Osob's development on April 9, 2002, at her nine month well child visit. Pet. Ex. 13, pp. 115-20. He referred Osob to Early Intervention ["EI"] services on May 8, 2002, noting that she had normal development until about nine months of age, but at that point she could not sit independently. *Id.*, pp. 111-14.

Osob received an MMR vaccine two months later at her one year well child visit on July 1, 2002. Pet. Ex. 13, p. 107. She was not seen again until August 29, 2002, and was diagnosed with a corneal abrasion. No concerns of vaccine reaction were expressed at this visit. *Id.*, pp. 101-03.

In the summer of 2002, Dr. Stratton remained concerned about Osob's persistent developmental problems. See, e.g., Pet. Ex. 13, p. 108. On December 31, 2002, about five months after receiving the July 2002 MMR vaccine, he noted that Osob exhibited mild language delays and her motor skills appeared to be worsening. *Id.*, p. 94. She was approximately 18 months of age at the time of this visit and was still unable to walk without assistance. *Id.*

At a follow up appointment on April 29, 2003, Dr. Stratton reported that with the help of intervention services, Osob had begun walking and spoke a few words, but still exhibited motor delay. Pet. Ex. 13, pp. 80-84. He twice expressed his suspicion that lack of stimulation or cultural issues were causal. *Id.*, pp. 88 (noting suspicion on Apr. 1, 2003), 94 (noting suspicion on Dec. 31, 2002).

Osob was formally diagnosed with developmental delay at Massachusetts General Hospital on June 16, 2003, when she was nearly two years old.¹⁶ Pet. Ex. 2.3, p. 24. Under the care of EI services, Osob gained milestones in both her motor and language development. See, e.g., Pet. Ex. 13, p. 84. Doctor Stratton noted that, at 28 months of age, Osob was walking better and could speak about 15-20 words. *Id.*, p. 59.

2. Events Leading to Autism Diagnosis.

In January 2004, at about two and half years of age, Osob began to lose developmental milestones. Pet. Ex. 13, p. 54. Early Intervention services re-evaluated Osob and found global delays, noting that she previously put two words together, but no longer spoke many words at all. *Id.* On January 22, 2004, Dr. Stratton noted that Osob

¹⁶ Doctor Stratton had used the International Classification of Disease Code for developmental delay in Osob's records prior to this date, but his narratives expressed concern rather than a definitive diagnosis. See, e.g., Pet. Ex. 13, pp. 80-84.

had been examined by a neurologist who indicated that she might have pervasive developmental disorder ["PDD"] or autism.¹⁷ *Id.*

Osob subsequently underwent a full neurodevelopmental evaluation at the Boston Children's Hospital on October 12, 2004. Pet. Ex. 8, pp. 5-12. According to the report, Osob had normal language development up until 18 months of age and began regressing at around 20 to 22 months of age. *Id.*, pp. 5-6. At the time of the evaluation, all of Osob's developmental milestones were delayed. *Id.* Additionally, Dr. Ronald E. Becker at the Children's Hospital found that Osob's regression and impaired social development were consistent with the diagnostic criteria for autism. *Id.*, p. 12.

On November 4, 2004, Dr. Stratton noted that Osob, then three years of age, had regressed to rare spoken words, such as "mama," "baby," and "hello," (Pet. Ex. 13, p. 8) and by late April 2005, nearing her fourth birthday, she became nonverbal (Pet. Ex. S). On April 27, 2005, neurologist Martha R. Herbert at the Massachusetts General Hospital noted that Osob had "complete lack of verbal language" in addition to developmental delay. Pet. Ex. S. She also concluded that Osob met all the criteria for autism disorder.

C. Osob from Five to Six Years of Age.

1. April 2006 Vaccinations.

Doctor Peter Masucci served as Osob's primary care physician beginning in late 2004. *See generally*, Pet. Ex. 7. Between November 2004 and February 2006, Osob presented to him on at least 16 separate occasions for a number of infections, including otitis media, acute sinusitis, and unspecified viral infections. *Id.*, pp. 15-16.

Osob received DTaP, MMR, and IPV vaccines at her five year well child visit on April 24, 2006. Pet. Ex. 18, p. 1; *see also* Pet. Ex. 7, p. 14. Doctor Masucci noted her history of autism, but indicated that she appeared well at the visit. Pet. Ex. 18, p. 2. Osob did not present to the pediatrician again until about a month later on May 30, 2006, when Dr. Masucci diagnosed her with an acute upper respiratory infection ["URI"]. Pet. Ex. 7, p. 14.

Osob continued to suffer from a number of infections from June 2006 through June 2007. Pet. Ex. 7, pp. 9-15. Based on the records, she was prescribed multiple

¹⁷ Pervasive developmental disorder or "PDD" is the umbrella term used in the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 4th ed. text revision 2000) ["DSM-IV-TR"] at 69, for certain developmental disorders, including autism (also referred to as autistic disorder), pervasive developmental disorder—not otherwise specified ["PDD-NOS"], and Asperger's Disorder. There is possible confusion between "PDD" (the umbrella term referring to the general diagnostic category) and "PDD-NOS," which is a specific diagnosis within the general diagnostic category of PDD. It is not uncommon for parents and even health care providers to use these terms in non-specific ways, such as referring to a child as having an "autism diagnosis," even though the specific diagnosis is PDD-NOS. In conveying that Osob may have "PDD/autism," the neurologist, Dr. Krishnamurthy, was likely referring to PDD-NOS and autism as specific diagnoses within the general category of PDD. The current DSM, DSM V, uses the term "Autism Spectrum Disorder" rather than PDD.

antibiotics during that year for various infections, including otitis media, pharyngitis, URI, sinusitis, and streptococcal sore throat. *Id.*, pp. 9-14, 21.

2. January 2007 Hospitalization.

Osob was seen by Dr. William E. Butler at the Massachusetts General Hospital on January 4, 2007, to discuss the results of her December 29, 2006 magnetic resonance imaging ["MRI"] scan, which revealed the appearance of an arachnoid cyst compressing the superior vermis of her cerebellum. Pet. Ex. 2.2, p. 2. Doctor Butler concluded that the progression of the cyst might be contributing to her gross motor imbalance.

On January 29, 2007, Osob underwent surgery to decompress the cyst. Pet. Ex. 2.3, p. 5. Shortly thereafter, on February 5, 2007, her physical therapist noted that Osob's motor skills were improving. Pet. Ex. 2.2, p. 18.

D. Osob's More Recent Medical History.

1. Primary Care Visits.

Doctor Marc A. Rosenthal served as Osob's primary care physician beginning in October 2007 until about March 2008. *See generally*, Pet. Ex. 6. On November 12, 2007, he expressed concerns about her severe regression, noting that Osob had no verbal language and did not follow general directions. *Id.*, p. 17. He was not convinced that autism was the most accurate diagnosis, but agreed that it defined her profile. *Id.*, p. 18.

Osob presented to Dr. Rosenthal again on January 18, 2008, for behavioral changes. Petitioners reported that recently Osob had become impulsively aggressive and appeared more irritated without apparent cause. Pet. Ex. 6, p. 11; see also Pet. Ex. 3, p. 7. They believed that the onset of these behavioral difficulties began a few months after Osob's surgery in January 2007 for cyst removal. Pet. Ex. 6, p. 12. During the evaluation, Dr. Rosenthal noted that Osob exhibited self-injurious behavior, hand flapping, an inability or refusal to follow commands, and lacked "social regard." *Id.* He also noted that Osob had no history of current illness and attributed her behavioral changes to the "evolution of her developmental disorder/autism" and not to "a specific NEW cause." *Id.* (emphasis original).

2. Events Leading to Mitochondrial Disorder Diagnosis.

On December 13, 2006, before her cyst surgery, Osob was evaluated at Learning and Developmental Disabilities Evaluation and Rehabilitation Services ["LADDERS"]. Pet. Ex. 3, pp. 1-2. Doctor Ann M. Neumeyer noted that Osob had continued to regress after the initial onset of regression at 18 months of age, and currently exhibited possible myopathy and proximal muscle weakness. She also

discussed the strong possibility of a genetic and metabolic disorder underlying Osob's developmental problems. *Id.*

Osob was subsequently evaluated at the Massachusetts General Hospital's Mitochondrial Disorders Clinic on August 15, 2007 by pediatric neurology resident Dr. David Dredge and attending physician Dr. Katherine Sims. Pet. Ex. 2.1, pp. 20-22. They noted that Osob had developed repetitive behaviors and stereotyped hand movements over the last few years and her parents were concerned that she was regressing. *Id.*, p. 20. However, they indicated that Osob had no history of frequent illnesses and, apart from Osob's initial regression, which was a common occurrence among autistic children, Osob had not exhibited any "clear regression or loss of skills in the last couple of years." *Id.*, p. 22.

Doctor Neumeyer authored a letter, dated October 25, 2007, indicating that Osob had a notable family history of autism in that her paternal cousin and paternal uncle both had autism spectrum disorder. Pet. Ex. 3, p. 5. She also indicated that Osob's muscle biopsy revealed "some nonspecific features with complex mitochondrial cristae and some subsarcolemmal clusters with enlarged mitochondria." *Id.*

On January 23, 2008, petitioners' related their concerns of behavioral changes in Osob to Dr. Neumeyer. Pet. Ex. 3, p. 7-8. Petitioners were worried that Osob's language skills were worsening and felt that her behavior was similar to what was seen prior to the cyst removal. However, Dr. Neumeyer noted that Dr. Rosenthal had found no etiology for Osob's behavioral changes and there was no current basis for concluding that it was related to a re-accumulation of the cyst. *Id.*

On February 6, 2008, Dr. Sims discussed the results of Osob's earlier muscle biopsy with Ms. Wedged, indicating that Osob had a mitochondrial complex I mutation and a selenium deficiency. Pet. Ex. 2.1, p. 17. At a follow up visit on April 2, 2008, Dr. Sims noted that, in addition to a complex I ETC deficiency, Osob also had "clinical features including autism-like global developmental delay, developmental regression, behavioral disorder and GI dysmotility." *Id.*, p. 12. Furthermore, she believed that Osob's selenium deficiency might be the cause of the myopathy. *Id.*, p. 13.

3. Most Recent Medical Records.

Following Osob's seventh birthday on July 9, 2008, Dr. Sims reported that Osob was in good health and showed "excellent and improving pre-language skills." Pet. Ex. 2.1, p. 10. By late January 2009, Osob had made great strides in learning sign language. *Id.*, p. 6.

In November 2012, the date of the most recent record, Osob remained nonverbal, and exhibited stereotyped vocal responses, sensitivity to noise, and difficulty in attending to environmental cues. Pet. Ex. 9, pp. 2, 6.

III. Applying the Facts to the Law.

A. Untimely Filing.

The Vaccine Act's statute of limitations provides in pertinent part that, in the case of:

a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury . . .

§ 300aa-16(a)(2).

Because petitioners filed the petition on behalf of Osob on April 22, 2008, the first symptom or manifestation of onset of Osob's autism cannot have occurred before April 22, 2005, in order for the petition to be considered timely. See *Markovich v. Sec'y, HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007) (holding that "either a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first"); *Cloer v. Sec'y, HHS*, 654 F.3d 1322, 1335 (Fed. Cir. 2011) (holding that the "analysis and conclusion in *Markovich* is correct. The statute of limitations in the Vaccine Act begins to run on the date of the occurrence of the first symptom or manifestation of onset."). Furthermore, the date of the occurrence of the first symptom or manifestation of onset "does not depend on whether petitioner knew or reasonably should have known" about the injury. *Cloer*, 654 F.3d at 1339. Nor does it depend on petitioner's knowledge as to the cause of injury. *Id.* at 1338.

In *Cloer*, the Federal Circuit also acknowledged that equitable tolling applies to Vaccine Act cases, but only under very limited circumstances, such as when a petitioner was the victim of fraud or duress, or when a procedurally deficient pleading was timely filed. *Cloer*, 654 F.3d at 1344-45. The Federal Circuit rejected the notion that equitable tolling should apply only because the application of the statute of limitations would otherwise deprive a petitioner from bringing a claim. *Id.*

The medical records establish, and petitioners appear to concede, that the claim was not timely filed. Doctor Stratton's records clearly convey that concerns regarding Osob's developmental delay existed as early as April 9, 2002. On May 8, 2002, Dr. Stratton indicated that Osob had normal motor development until nine months but, at ten months, she could not sit well. Pet. Ex. 13, p. 114. Additionally, a number of medical records note that Osob had normal cognitive development until 18 months of age (see Pet. Exs. 3, p. 1; 5, p. 29; 8, p. 5), which places the onset of her developmental delay in late December 2002. I thus find that the first symptom or manifestation of Osob's autism spectrum disorder occurred long prior to the critical date of April 22, 2005.

Even if the Vaccine Act's statute of limitations ran from the date of diagnosis and not the first symptom or manifestation of onset, this case would still be untimely filed as Osob was diagnosed with autism in October 2004, six months prior to April 22, 2005.

Petitioners have not asserted any extraordinary circumstances which would merit equitable tolling of the Vaccine Act's statute of limitations. I therefore conclude that this case was untimely filed.

B. Significant Aggravation.

To recover under a significant aggravation theory, petitioners must demonstrate that the vaccination caused a "change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration in health." § 33(4); *Hennessey v. Sec'y, HHS*, No. 01-190V, 2009 WL 1709053 at *1 (Fed. Cl. Spec. Mstr. May 29, 2009), *aff'd*, 91 Fed. Cl. 126 (2010). In *Loving v. Sec'y, HHS*, 86 Fed. Cl. 135, 144 (2009), the Court of Federal Claims created a six-factor test for significant aggravation, requiring a petitioner to establish by preponderant evidence: (1) the vaccinee's condition prior to administration of the vaccine; (2) the vaccinee's current condition or condition following the vaccine; (3) whether the comparison of the two conditions constitutes a significant aggravation of the person's condition; (4) a medical theory causally connecting a significantly worsened condition to the vaccine; (5) a logical sequence of cause and effect demonstrating that the vaccine was the reason for the significant aggravation; and (6) a proximate temporal relationship between the vaccine and the significant aggravation. This test has been cited with approval by the Federal Circuit. *W.C. v. Sec'y, HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013).

Osob was diagnosed with autism in October 2004 and had been suffering from developmental problems at the time she received the April 2006 vaccinations. See Pet. Ex. 8, pp. 5-12. Following her April 2006 vaccines, she next sought medical care over a month later when she was seen for a URI. She was seen for a number of infections in the following year, received surgery for a brain cyst, and made gains in motor skills subsequent to the surgery. The first contemporaneous medical record to note regression was at a primary care visit in November 2007, 19 months after the April 2006 vaccinations. In a non-contemporaneous history recorded in January 2008, petitioners dated Osob's regression to a few months after the January 2007 surgery, placing onset of the regression about one year after the April 2006 vaccinations. Additionally, both Dr. Rosenthal and Dr. Neumeyer considered the progression of Osob's developmental problems as consistent with her autism diagnosis. See Pet. Exs. 6, p. 12; 2.1, p. 22. Thus, it appears there is no close temporal connection between Osob's worsened symptoms and the April 2006 vaccinations.¹⁸

¹⁸ On July 16, 2012, petitioners filed an affidavit from Mr. Hashi. He indicates that after receiving vaccinations on April 22, 2006, Osob's behavior changed. For example, she started to bite things, make loud vocalizations, have irregular sleep, and became non-verbal. Pet. Aff. at 2-3. The symptoms listed in his affidavit do not match those contained in the contemporaneous medical records. Conflicts between contemporaneous medical records and subsequent statements are common in Vaccine Act cases, with

III. Conclusion.

The Vaccine Act provides that “no petition may be filed . . . after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury.” § 16(a)(2). There is preponderant evidence that the causation in fact claim was not filed within the 36-month period and petitioners have failed to demonstrate any extraordinary circumstances warranting equitable tolling. **Therefore, petitioners’ causation in fact claim is dismissed.**

The contemporaneous record fails to demonstrate any proximate temporal relationship sufficient to support a colorable significant aggravation claim, suggesting petitioners lack a reasonable basis to proceed on a significant aggravation theory. Nevertheless, if petitioners intend to pursue such a claim, as is suggested by their response to respondent’s motion to dismiss, they must file a second amended petition by no later than **Wednesday, September 25, 2013**. Additionally, petitioners must file an expert report supporting a significant aggravation claim by **Monday, November 25, 2013**. **A failure to meet these deadlines will result in dismissal of this petition.**

IT IS SO ORDERED.

s/Denise K. Vowell

Denise K. Vowell
Special Master

Special masters frequently according more weight to the contemporaneously recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony. “It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.” *Murphy*, 23 Cl. Ct. at 733 (1991). See also *Cucuras v. Sec’y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec’y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by “clear, cogent, and consistent testimony” explaining the discrepancies. *Stevens v. Sec’y, HHS*, No. 90-221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr., Dec. 21, 1990).